

MAR 4 2002

**510(k) Summary**

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, NxStage, Inc. is required to submit with this Pre-Market Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." NxStage chooses to submit a summary of information respecting safety and effectiveness.

**Date:** December 3, 2001

**Common/Usual Name:** Accessories to hemodialyzer

**Trade/Proprietary Name:** NxStage™ MLA Multi-Line Adaptor  
NxStage™ SFR Sterile Fluid Reservoir

**Classification Name &  
Device Classification:** Dialyzer, High Permeability with or without Dialysate System; Class II

**Product Code:** KDI

**21 CFR Ref.:** 876.5860

**Device Panel:** Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

**510(k) Sponsor &  
Owner/Operator:** NxStage Medical, Inc  
439 South Union St, Suite 501  
S. Lawrence, MA 01843  
Owner/Operator No. Not yet assigned

**Contact Person:** Karen St.Onge (Contact Person)  
Director, Quality Assurance/Regulatory Affairs

**Device Description:**

The SFR Sterile Fluid Reservoir and MLA Multi-Line Adaptor are accessories intended for use with the NxStage™ Hemofiltration System. The NxStage System is indicated for treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration.

The MLA Multi-Line Adaptor is used for connecting multiple containers of replacement solution to the NxStage Cartridge or NxStage SFR.

The SFR Sterile Fluid Reservoir is used for the containment of replacement solution or waste fluid.

**Predicate Device:**

Substantial equivalence for the proposed accessories to the LifeMate™ Cartridge is based on similarities between these proposed new accessories and the existing LifeMate™ Cartridge, which was found substantially equivalent in FDA's review of K001283. The proposed NxStage accessories are also similar in design and intended use to peritoneal dialysis system accessories marketed by Baxter Healthcare Corporation and Fresenius USA, Inc.

**Safety and Performance:**

Substantial equivalence for these devices was based on testing (tensile, leak and simulated use) conducted to confirm that the SFR and MLA products meet minimum specifications developed by NxStage to establish fitness for use. Product safety in terms of biocompatibility is based on similarities between the materials used to manufacture the SFR and MLA products, and other NxStage products cleared for marketing via Pre-Market Notification.

**Conclusion:**

Based on the device indications for use, comparison of descriptive and technological characteristics, and design control certification, the NxStage Multi-Line Adaptor (MLA) and NxStage Sterile Fluid Reservoir (SFR) have been shown to meet the minimum requirements that are considered acceptable for their intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 4 2002

Ms. Karen St.Onge  
Director, Quality Assurance/Regulatory Affairs  
NxSTAGE Medical, Inc.  
439 S. Union St.  
5<sup>th</sup> Floor  
LAWRENCE MA 01843

Re: K011269

Trade/Device Name: NxStage™ MLA -  
Multi-Line Adaptor and  
NxStage™ SFR -  
Sterile Fluid Reservoir

Regulation Number: 21 CFR §876.5860

Regulation Name: High permeability  
hemodialysis system

Regulatory Class: II

Product Code: 78 KDI

Dated: December 3, 2001

Received: December 4, 2001

Dear Ms. St.Onge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

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510(k) Number (if known): K011269

Device Name: NxStage MLA-Multi Line Adaptor  
NxStage SFR- Sterile Fluid Reservoir

### Indications for Use:

The NxStage Hemofiltration System is indicated for treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration. All treatments must be administered by a health care provider, under physician prescription.

The NxStage MLA Multi-Line Adaptor and SFR Sterile Fluid Reservoir are accessories intended for use with the NxStage System for the treatment of renal failure or fluid overload using hemofiltration and/or ultrafiltration.

The NxStage MLA Multi-Line Adaptor is used for connecting multiple containers of replacement solution to the NxStage Cartridge or NxStage SFR.

The NxStage SFR Sterile Fluid Reservoir is used for the containment of replacement solution or waste fluid.

*David H. Seymour*  
**(Division Sign-Off)**

**Division of Reproductive, Abdominal,  
and Radiological Devices**

510(k) Number K011269

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-the -Counter Use ☐